	IRP Initial Validation checklist	
1	Applicant's reference (if applicable)	
2	Reference regulator	Select RR
3	If the RR is a EU member state please specify	Select EU MS
4	Date of approval of the reference product in the RR state	
5	Declaration of conformity of the GB application with the dossier that received a positive opinion from the CHMP [and was approved by the EC if the EC decision has already been received], including all facilities and lines of manufacture, analysis and batch release and approved variations.	☐
6	Confirmation that MAH based in EEA and Marketing Authorisation Holder for the application(s) is the same company or belongs to the same (legal) group of companies as the MAH in the reference procedure.	☐
7	Declaration that all iterations (full and summaries) of the Reference Regulator assessment reports have been provided in the dossier All the assessment reports included are listed in Annex 1 below	☐
8	Are there conditions associated with the reference regulator approval If yes the details should be included in M-1-0 Cover documents	No
9	Are there difference in the wording in the proposed therapeutic indications for the UK application and the therapeutic indications approved by the RR	Yes
	If applicable Justification for these changes has been provided in the M-1-0 Cover documents	☐
	A justification for the Adverse Drug Reactions (ADRs) listed in the SmPC, or a statement that says where in module 2 the justification is.	☐
10	Is a new ASMF being used in support of this application	No
	If yes a declaration has been provided by the ASMF holder that the Applicant and Restricted part of the ASMF and letter of access have been provided and all iterations of the assessment reports are included in the submission from the ASMF holder.	☐
	Letter of access has been provided in M-1-2 Annex 5.10	☐
11	Are there differences in the proposed UK Risk Management Plan compared to the RMP approved by the RR (if applicable)	No
	Where there are differences in the proposed safety concerns, additional pharmacovigilance activities or additional risk minimisation measures, brief details are provided in Annex II below	☐
	Is the GB/UK specific Annex (Guidance-on-pharmacovigilance-procedures) used and included with the RMP in M-1-8-2	☐
12	For this application, has the product been approved, withdrawn, refused or rejected by any other RR? Approved ☐ Withdrawn ☐ Refused ☐ Rejected ☐	
13	Confirmation of the EU-agreed outcome of the nitrosamine risk evaluation for step 1, 2 and 3, as appropriate:	☐
14	Is Orphan designation being requested as part of the application	☐

	If yes, the GB Orphan Application form been provided in Module 1.2	☐
15	RR product information provided in M1 additional data	☐
16	Qualified person responsible for pharmacovigilance who resides and operates in the UK or the EU/EEA	☐
	Address where the pharmacovigilance system master file for the medicinal product can be accessed electronically, in the UK	☐
	Annex 1 List of assessment report	
	Annex 2 Differences in RMP	
	Annex 3 Reasons for withdrawal, refusal or rejection	