AGENZIA ITALIANA DEL FARMACO

Risk evaluation outcome-Step 1

I herewith confirm that, the requested risk evaluation applying principles outlined in the CHMP's Article 5 (3) opinion EMEA-H-A5(3)-1490 have been performed. The review performed is adequately documented and risk evaluation documentation can be made available upon request.

Marketing Authorisation Holder
(name and address)

Product name

API name

Marketing Authorisation Number (six digits)

National or MRP/DCP product ---

EU Procedure Number (for MRP/DCP products only)

IT RMS/CMS ---

Biological product ---

Risk identified ---

If YES, fill in the following fields:

Confirmatory testing is planned to start on

(Insert timeline for confirmatory testing MM/YY)

Results are expected by

(Insert timeline MM/YY)

An update will be provided by

(Insert timeline MM/YY)

Risk identified in (select one or more entries)

☐ Finished product

☐ API

☐ API intermediate

☐ Primary packaging

Indicate the manufacturing site related to the potential root cause of contamination

Finished Product Manufacturer (name and address)

Name	Address

API Manufacturer (name and address)

Name	Address

Intermediate Manufacturer (name and address)

Name	Address

Intermediate name (if identified as contamination root cause)

Contamination root cause description (if identified)

Notes

Name of the legal representative or delegate